

REMARKS

Applicants have amended the claims in order to more particularly define the invention taking into consideration the outstanding Official Action. Claims 20 through 24 have been added to the application to further specific aspects of the invention as set forth on page 10, lines 32-33 and page 11, line 11 of Applicants' specification. Claims 20-22 specify that the lactose monohydrate crystals have an elongation ratio of 1.58 ± 0.33 and a size in the range of 63 to 90 μm . Claims 23 and 24 specify the elongation ratio support on page 11. Applicants most respectfully submit that all of the claims now present in the application are in full compliance with 35 U.S.C. 112 and are clearly patentable over the references of record.

The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite has been carefully considered but is most respectfully traversed. As is noted by the Examiner, claim 5 contains reference to "carbopol 93™" which is a trademark. However, Applicants most respectfully submit that one of ordinary skill in the art would clearly recognize the content of this trademark based upon information well known to one of ordinary skill in the art to which the invention pertains. Applicants submit herewith copies of data sheets with respect to this material and submit that the claim would not be indefinite to one of ordinary skill in the art to which the invention pertains. The level of skill must be taken into consideration in evaluating the scope of the claims. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 1-3, 8 and 9 under 35 U.S.C. 103 as being unpatentable over Hirao et al. has been carefully considered but is most respectfully traversed.

In the Official Action, it is urged that Hirao teaches a process of shaping crystals of sugar alcohols by obtaining a saccharified starch solution with high maltose content, allowing crystallization and separation. The Examiner notes that the viscosity of the solution can be regulated by addition of water-soluble organic solvent or elevated temperature. It is further noted that Hirao does not teach viscosity of less than 25 Pa.s at shear rate of 1s^{-1} . This rejection has been carefully considered but is most respectfully traversed.

At the outset, Applicants wish to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP § 2143. This section states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants also most respectfully direct the Examiner's attention to MPEP § 2144.08 (page 2100-114) wherein it is stated that Office personnel should consider all rebuttal argument and evidence present by applicant and the citation of In re Soni for error in not considering evidence presented in the specification.

Applicants wish to point out that Hirao et al. is directed toward a very specific problem, i.e. a method for producing anhydrous crystals of maltitol. There is nothing in the teaching of this document to suggest to the skilled person that this methodology would have wide applicability as does the presently claimed invention.

It is recognized in the Official Action that Hirao does not teach a viscosity of less than 25 Pa.s at a shear rate of $1s^{-1}$. It is further urged that no criticality is seen in the particular viscosity since the prior art obtains the same result desired by Applicants, e.g. a crystalline composition that is non-hygroscopic, free-flowing and can be any desired size and shape. It is then conclude that it would have been prima facie obvious for one

of ordinary skill in the art by routine experimentation to determine a suitable viscosity of the solution to obtain the claimed invention. This aspect of the rejection is specifically traversed.

The fact that a crystalline composition is obtained does not alter the fact that the obviousness of the claimed subject matter must be considered in light of the claim limitations which include the viscosity range as set forth in the claims. There must be motivation in the prior art to make the necessary changes to the process and Applicants' specification may not be used as a teaching reference. Absent the suggestion in the prior art with respect to the viscosity range and steps specified in the rejected claims, there is no expectation of success and therefore the rejection should be withdrawn.

Ref. col. 7

The rejection of claims 4, 5 and 10 under 35 U.S.C. 103 as being unpatentable over Hirao et al. and Douglas et al. has been carefully considered but is most respectfully traversed for the reasons set forth with respect to the prior art rejection over Hirao et al. alone. Applicants note that it is urged in the Official Action that Hirao et al. is silent as to the teaching of the carbomers as a starch or binder in an aqueous solution. Silence in a reference is not a substitute for the necessary teaching to arrive at the claimed invention. ~~Douglas~~ is relied upon for teaching of an oral administration composition comprising starch or carbomers as an aqueous solution thickener. It is then concluded that it would have been obvious from one of ordinary skill in the art to modify Hirao's starch solution using carbomers taught by Douglas. The unexpected result is said to be free-flowing crystalline having the desired size and shape. Again, this rejection is clearly based upon hindsight and Applicants' specification may not be used as a teaching reference to arrive at the presently claimed invention. In re Fritch, 23 USPQ 1780, 1784(Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.).

Applicants wish to point out that Douglas et al. describes a ranitidine composition which is substantially free of bitter taste which in no way overcomes the deficiencies in

the teachings of the Hirao et al reference. The combination of references does not render the presently claimed invention obvious.

Applicants wish to note that crystals prepared according to the presently claimed invention have significantly higher mean elongation ratio and surface smoothness as discussed on page 10 of the present specification. See also page 11 of Applicants' specification. Moreover, data within this specification at page 28 demonstrates that increasing the surface smoothness and elongation ratio gives rise to an increase in the fine particle fraction (FPF) of the drug delivered. Hirao et al is silent as to these crystalline properties which are not suggested by the prior art. A skilled person would not be motivated to use in Hirao et al process in the expectation of producing crystals improved with these inhalation properties. Douglas et al. does not teach the use of an aqueous solution of carbomer as being a medium suitable for use in a crystallization process. The equivalence of starch and carbomers is not used in the same context as that of the present invention. Accordingly, it is most respectfully requested that this rejection be withdrawn.

→ The rejection of claims 7, 12, 13, 18 and 19 under 35 U.S.C. 103 as being unpatentable over Hirao et al. has been carefully considered but is most respectfully traversed.

In the Official Action, it is urged that Hirao et al. is relied upon for the reason stated in the previous rejection. The Examiner appreciates that Hirao does not specify the specific ^{sugar} alcohol, lactose monohydrate. However, Hirao et al does teach other sugar alcohols such as sorbitol, maltitol or 'maltose monohydrate at columns 2-4. It is concluded in the Official Action that it would have been obvious for one of ordinary skill in the art by routine experimentation to select lactose monohydrate as one of the well known sugars to obtain the claimed invention. This aspect of the rejection is clearly traversed as there is absolutely no suggestion which would lead one of ordinary skill i the art to make the selection other than Applicants' own specification which may not be used as a teaching reference. Obvious to try is not the standard of obviousness under 35 U.S.C. 103. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Applicants most respectfully submit that the application clearly contains an allowable generic claims and the subject matter withdrawn from consideration should be considered and be allowed in view of the allowable generic claims.

Applicants note that an information disclosure statement was filed with the preliminary amendment listing the references cited in the International Search Report. The copy of the Notification of Acceptance indicates receipt of the Search Report and of the copies of the references. Accordingly, it is most respectfully requested that the initialed and date Form 1449 be returned with the next Official Action.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all the claims now present in the application are most respectfully requested.

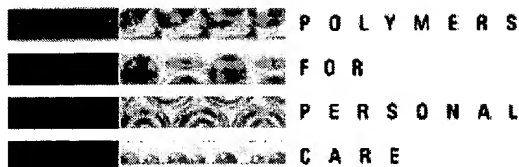
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May 14, 2002



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**Carbopol® 934,940, 941 Polymer
Product Specifications**

GENERAL

Solution Appearance: White Powder
Odor: Slightly Acetic

	% SOLUTION	MINIMUM	MAXIMUM	TEST FREQUENCY	BFG PROCEDURE NUMBER
Brookfield RVF or RVT Viscosity, cP:					
(20 rpm at 25° C, neutralized solutions)					
Carbopol 934	0.2%	2,050	5,450	Each Lot	430-I
	0.5%	30,500	39,400	Each Lot	
Carbopol 940	0.2%	19,000	35,000	Once/20 Lots	430-I
	0.5%	40,000	60,000	Each Lot	
	1.0%	45,000	80,000	Once/20 Lots	
Carbopol 941	0.05%	700	3,000	Once/20 Lots	430-I
	0.2%	1,950	7,000	Once/20 Lots	
	0.5%	4,000	11,000	Each Lot	
Moisture Content:	--	--	2.0%	Once/10 Lots	SA-004
Carbopol 934	--	--	2.0%	Once/10 Lots	SA-004
Carbopol 940	--	--	2.0%	Once/10 Lots	SA-004
Carbopol 941	--	--			
Heavy Metals: (Pb, As, Hg, Sb)	--	--	10 ppm	Once/200 Lots	SA-012
Clarity, % Transmission:					

(Neutralized solution, 420 nM light) Carbopol 940	0.5%	0.5%	--	Each Lot	400-D
Residual Benzene, %:	--	--	0.5%	Each Lot	SA-006

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Ultrez
 POLYMERS

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Carbopol® 934

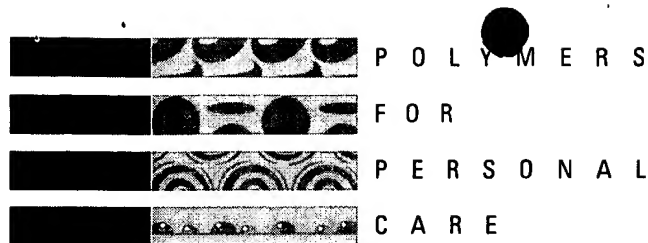
Carbopol® 934 offers excellent stability at high viscosity and produces thick formulations such as heavy gels, emulsions and suspensions. In aqueous systems, Carbopol® 934 polymer exhibits short flow (quick recovery) properties. Suggested applications include lotions and creams.

Carbopol® Ultrez™ 10, the latest in the Carbopol® polymer family, offers performance properties similar to those of Carbopol® 934, and additional benefits such as ease of dispersion and a broader range of applications.

Formulations **MSDS** **Specification Sheet** **Technical Data Sheets** **Toxicology Data**

Technical data sheets for Carbopol® 934:

<u>TDS 57</u>	General Rules for Order of Ingredient Addition
<u>TDS 60</u>	Applications Technology of Carbopol® Resins and Cosmetic Formulations
<u>TDS 61</u>	How to Prepare Aqueous Dispersions of Carbopol® and Pemulen® Polymers
<u>TDS 103</u>	Dispersion Techniques for Carbopol® and Pemulen® Polymers
<u>TDS 237</u>	Neutralizing Carbopol® and Pemulen® Polymers in Aqueous and Hydro-alcoholic Systems
<u>TDS 244</u>	Measurement and Understanding of Yield Value in Personal Care Formulations
<u>TDS 85F</u>	Status of BFGoodrich Products in Meeting Various Monographs
<u>TDS 164</u>	Biotreatability of Carbopol® Polymers
<u>Publication</u>	Final Report on the Safety Assessment of Carbomer 934, 910, 934P, 940, 941 and 962



BFG **drich**

TDS 60
Rev. July 1997

Applications Technology for Carbopol® Resins and Cosmetic Formulations

BFGoodrich introduced Carbopol® 934 resin to the cosmetic industry in the middle 1950's. Since that time, a number of these products have been introduced. Those resins of most interest to the cosmetic chemist have been assigned the CTFA generic names of Carbomer 934, 940 and 941. These complementary products continue to meet the exacting ever-changing demands of advanced cosmetic products because of the properties Carbopol® resins provide.

Safety: A 25 year history demonstrating non-irritating, non-sensitizing use.

Elegance: Luxurious feel.

Stability: Assured shelf life and performance.

Efficiency: Effectiveness at very low concentrations.

Microorganism Resistance: No support for bacteria, mold, or fungus growth.

Quality: Assured, uniform performance.

Versatility: Performance across wide pH and viscosity ranges.

The aim of this paper is two-fold. The first is to provide a brief review of the fundamentals of Carbopol® resins technology. The second is the application of this technology to product formulation and production.

Technology Overview

All the Carbopol® resins are dry, polyacrylic acid resins. When first dispersed in water or other solvent, they are tightly knotted together via hydrogen bonding. At normal use levels of up to 1% (Figure 1) no significant thickening occurs until the resins are partially neutralized with an appropriate base to form a salt. When this salt dissolves and ionizes, it swells into its most effective thickening form (Figure 2).

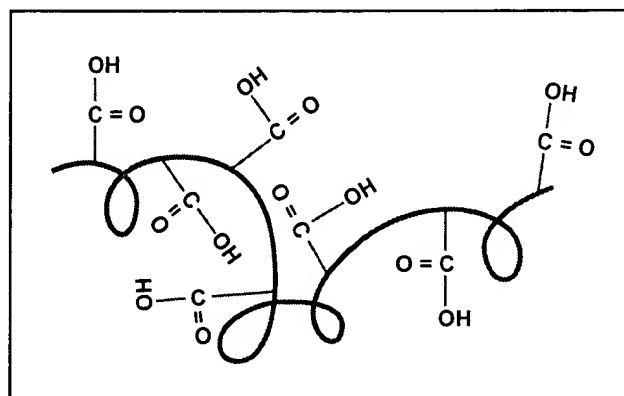
An electronic repulsion network gives the Carbopol® resins their efficiency (Figure 3). The Carbopol® resins are usually only partially neutralized since complete sodium hydroxide neutralization, for example, would produce a pH in excess of 10.

All of the Carbopol® resins operate via the same mechanism but each has its own attributes. Note, for example, the difference in viscosity development (Figure 4). Here, the resins have been neutralized to pH 7 with sodium hydroxide.

In addition, the optimum pH operating range varies somewhat with the Carbopol® resin (Figure 5). Note that with Carbopol® 940, the optimum pH operating range is from 3 to 11. Curves for the other Carbopol® resins are similar in shape but of different values.

A more appropriate description of Carbopol® resin performance would be as flow control agents. The reason for this is that once swollen, they generate

Figure 1
Schematic Depicting Molecule of Carbopol Resin in Relaxed State



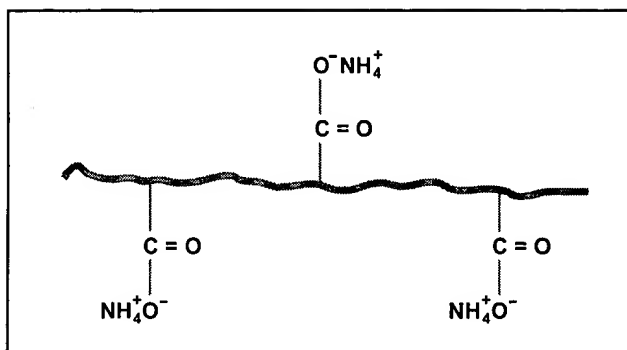
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ETD™ POLYMERS

CARBOPOL
Ultrez™
POLYMER

PEMULEN
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Figure 2
Schematic Depicting Molecule of Carbopol Resin in Uncoiled State



plastic flow systems and these systems exhibit the rheological property of Yield Value. Yield Value can be defined as an initial resistance to flow under applied stress. It is this property that elevates the Carbopol® resins above mere thickeners.

The importance of Yield Value in stabilizing emulsions and suspensions is that Yield Value is an opposing force to the gravitational movement of the dispersed phase and Yield Value accompanies viscosity generation with the Carbopol® resins. In addition to stabilizing emulsions and suspensions from separation, it provides freeze-thaw stability as well.

Figure 3
Effect of pH on Viscosity of a 0.5% Solution of Carbopol Resin in Water

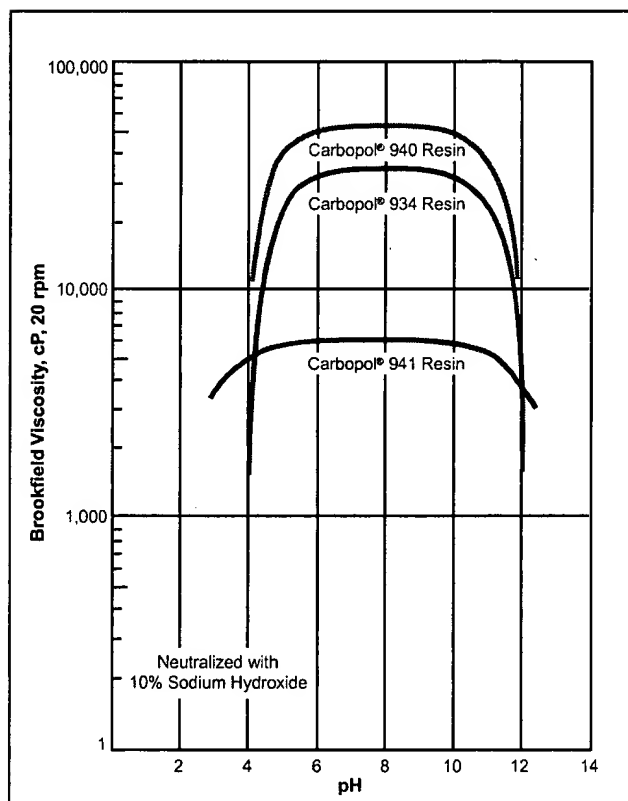
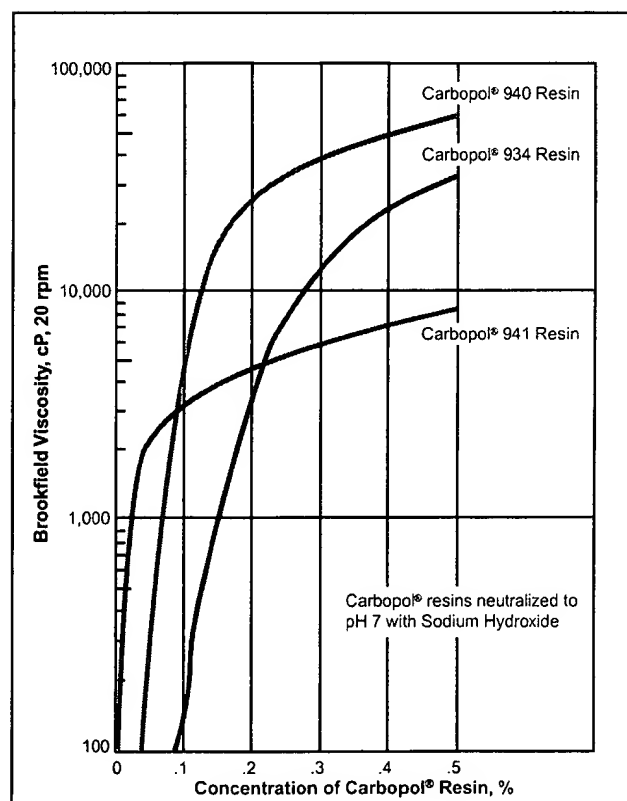


Figure 4
Thickening Efficiency of Carbopol Resins at Low Concentrations in Water



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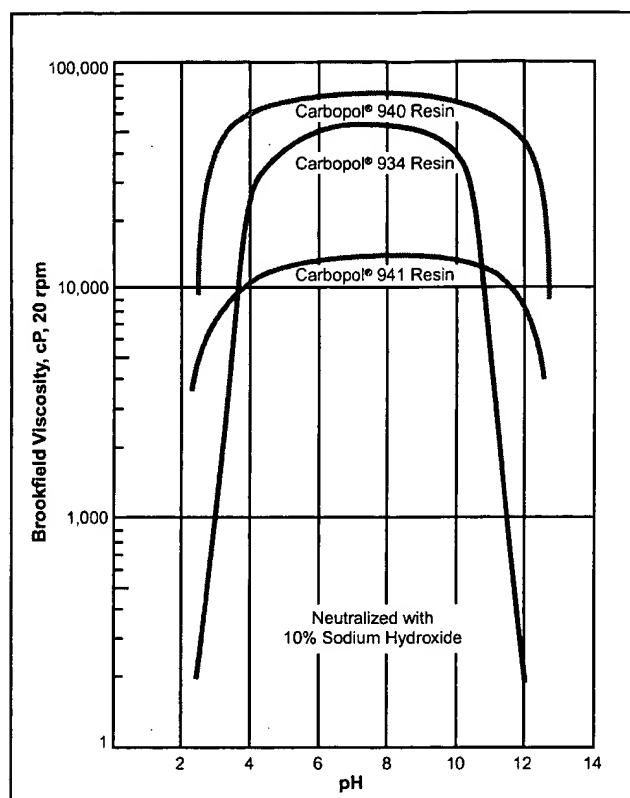
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Figure 5
Effect of pH on Viscosity of a 1.0% Solution
of Carbopol Resin in Water



An important point is that Yield Value imparts stability without the need for overwhelming viscosity. The gravitational pull on a suspended particle is directly proportional to the square of its diameter, (when the particles approach molecular size) the difference in specific gravities of the continuous and dispersed phases, and inversely proportional to the viscosity. Selection of the proper Carbopol® resin is simplified by the following table.

Selecting the Right Carbopol® Resin

<u>Requirement</u>	<u>Recommended Carbopol® Resin</u>
Clear gels > 3000 cP	940
Suspensions or emulsions at > 3000 cP	934, 940
Suspensions or emulsions at < 3000 cP	941
Higher shear resistance	934, 940
Better ion resistance	941
Better thermal stability	934, 940

*Brookfield, 20 rpm, viscosities

Neutralization

Having chosen a candidate resin, one then asks what neutralizing agent (base) to employ. Sodium or ammonium hydroxide, are useful as well as a variety of amines. Historically, alcoholic amines, such as triethanolamine, with low odor and color have been favored. Amines pose no threat of over-neutralization (with the subsequent viscosity loss) that is possible with alkali-metal hydroxides. Lower molecular weight amino acids, as neutralizing agents, form interesting Carbopol® resin salts due to their moisturizing contribution.

Recent concerns about nitrosamine-forming agents in cosmetics has stimulated a search for alternative neutralizing agents. Quadrol (BASF-Wyandotte) may be suitable. Quadrol is a very interesting neutralizing agent. It is useful in all-water or alcohol-water systems containing up to 50% alcohol. As with any material, one should contact the supplier concerning toxicological considerations.

Other valuable characteristics of these versatile Carbopol® resin products are often overlooked or poorly appreciated. Let's consider the whole Carbopol® resin character.

Acidic Nature

The Carbopol® resins are polyacrylic acids. This means they are very hydrophilic. Secondly, the Carbopol® resins are anionic products that will normally react with any cations. The cations of neutralizing bases are well known to form a salt of the polymer. It is not always appreciated that cationic conditioning agents can also react with, and precipitate, the Carbopol® resins.

As acid products, just how acidic are the Carbopol® resins? The following table shows the ionization constants of several mild acids contrasted with that of Carbopol® 934:

<u>Acid</u>	<u>Ionization Constant</u>
Citric	75000 X 10 ⁻⁷
Acetic	1800 X 10 ⁻⁷
Carbonic	4.5 X 10 ⁻⁷
Carbopol® 934	1.6 X 10 ⁻⁷

If ionization constant is considered a reasonable measure of acid strength, then the Carbopol® resins are extremely mild. Nevertheless, they are active anions and will be sought by any cations in the system.

Colloidal Nature

It is quite likely that each particle of Carbopol® resin is an individual molecule - a kind of three dimensional, hydrophilic network about 2 to 4 microns in diameter, i.e., super colloids. Many studies have confirmed that these swollen particles display a significant electrical charge, especially after neutralization, and attract each other. This particle to particle attraction explains Yield Value.

It is then easy to visualize the well-known shear recovery displayed by all the Carbopol® resin systems. The application of shear separates the particles, but they are rapidly snapped back together by electronic attraction upon shear release. For optimum Carbopol® resin service, consider the influence of any ingredients, such as salts or extraneous cations in the formula, that reduce this attraction, and hence, the Carbopol® resin's viscosity and Yield Value.

Looking at the total Carbopol® resin character then, one can assure success in employing these high-polymer, base-actuated, hydrophilic, colloidal, flow control agents.

Technology Application

A company was producing a cream shampoo, thickened with Carbopol® 934, containing sodium lauryl sulfate (SLS). Suddenly, without a formulation or equipment change, the production viscosities went out of specification.

The problem? An aggressive buyer had purchased a cheaper grade of SLS containing a higher level of sodium sulfate. This ionic material was reducing the Carbopol® resin's swelling capability. To correct the problem was easy: return to the original SLS. A slight increase in Carbopol® resin level could also have solved the problem.

Frequently, order of addition, and/or choice of neutralizing agent, can avoid an interfering reaction. Water-based zinc oxide ointments have been successfully produced with Carbopol® resin products for years. However, care is necessary. A dispersion of zinc oxide, water, Carbopol® resin and sodium hydroxide quickly turns to a lumpy, cottage cheese consistency. Carbopol® resin will have its cation, and the zinc oxide offers a swamping concentration.

If one considers order of addition and neutralizer selection, success is possible. By first neutralizing the Carbopol® resin dispersion to a pH greater than

7.2 (with a strong base such as sodium hydroxide) and then adding the zinc oxide, a mixed, sodium-zinc half salt forms which results in a smooth, stable ointment.

But many times, an interaction expresses itself much more subtly.

Hair Setting Gel

	<u>% By Weight</u>
PVP or protein film former	2
Water	q.s. 100
Triethanolamine	0.5
Carbopol® 940	0.5
Disodium EDTA	0.005
UV Absorber	0.005
Methyl paraben	0.1
Propyl paraben	0.1
Color	q.s.
Perfume	q.s.
Solubilizer	q.s.

If one neglects the fact that Carbopol® 940 is a high-polymer, acidic colloid, one is likely to disperse it with all the other ingredients in the water, and add the TEA as the last step. A smooth, stable gel will form if this is done.

However, polyvinylpyrrolidone (PVP) and protein film formers are somewhat cationic and flocculate the Carbopol® resins. This flocculation is reversed upon addition of the TEA, but gel clarity is frequently adversely affected.

To avoid this interaction, either neutralize the Carbopol® resin dispersion before addition of the PVP or protein or add the TEA combined with the PVP or protein.

Note in this formulation the use of Di-sodium EDTA and a UV absorber. Unprotected, clear, Carbopol® resin gels, packaged in clear containers and exposed to light, gradually lose viscosity; and the loss is permanent. Generally, this can be effectively inhibited with the use of one percent Di-sodium EDTA plus one percent UV absorber, with both percentages based on the weight of the Carbopol® resin present. This stabilization is normally unnecessary in Carbopol® resin products such as creams and lotions.

Sparkling Sunscreen Lotion

This formulation can be easily handled because there is no significant interaction of the actives with the Carbopol® resin and the ethanol offers simple addition.

Sparkling Clear Sunscreen Lotion

<u>Ingredients</u>	<u>Parts</u>
Ethanol	16.0
H ₂ O	50.0
Carbopol® 941	1.0
Arlamol E ⁽¹⁾	20.0
Amerscreen P ⁽²⁾	10.0
Brij-98 ⁽³⁾	1.0
Quadrol ⁽⁴⁾ (50% water solution)	2.0
Brookfield Viscosity, cps	2,630

⁽¹⁾ Arlamol E ICI America

⁽²⁾ Amerscreen P Amerchol

⁽³⁾ Brij-98 ICI America

⁽⁴⁾ Quadrol BASF/Wyandotte

Rather than disperse the Carbopol® resin in the water or add stock Carbopol® resin dispersion, add, with stirring, the Carbopol® resin to the alcohol (a dump-in procedure). Then add all the other actives. When these are evenly dispersed, add the water. This results in a thin, easily stirred dispersion. Add the Quadrol last to produce thickening.

This procedure minimizes air entrapment and simplifies production. This level of sunscreen usually protects the Carbopol® resins, but should unacceptable viscosity loss occur, addition of Di-sodium EDTA should be considered.

Beating Bubbles

Sometimes bubble content in a clear gel Carbopol® resin system must be controlled to satisfy marketing goals. The goal may be zero bubbles or, again, "just the right amount" to add visual appeal. The two major sources of bubbles are from mechanical entrapment and chemical generation.

Minimize mechanical bubble formation by careful dispersion of the Carbopol® resins and by arranging for air bubble release before neutralization. In simple systems, this can be handled by allowing the dispersion to stand. In sophisticated systems, vacuum de-aeration (or even vacuum mixing) readily eliminates bubbles.

Another method to control bubble inclusion is to avoid disturbing the gel-air interface. Even slow speed mixers, that break the gel surface mechanically, incorporate air. Be certain impellers are large, low speed sweep types that are entirely submerged. Such systems should slowly turn over the gel and can de-aerate in the process.

Filling equipment must be flooded, purged of air, and kept flooded to avoid air inclusion. Look to the packings on a piston tuber, for example, to avoid air injection.

A frequent cause of bubbles, especially myriads of tiny ones, is neutralizer that has become carbonated upon exposure to air. When added to the acidic Carbopol® resin dispersion, the CO₂ is liberated. To avoid this, store neutralizing agents in closed containers. On a production basis, careful inventory rotation of the neutralizer can minimize the problem.

Conclusion

Carbopol® resin products have complexities that contribute to their ultimate performance. An understanding of these complexities assures the professional chemist successful production formulation, production and performance.

Many of the listed ingredients may require special handling. It is the user's responsibility to obtain and follow the current recommendations and safety precautions of the individual additive supplier.

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